

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

To:
RICHARD J. WARBURG
FOLEY & LARDNER LLP
P.O. BOX 80278
SAN DIEGO, CA 92138-0278

PCT

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

RECEIVED

JAN 18 2006

I.P. DEPT.
FOLEY & LARDNER

Due
3-11-06

Date of mailing (day/month/year)	11 JAN 2006
Applicant's or agent's file reference 034827-3102	FOR FURTHER ACTION See paragraphs 1 and 4 below
International application No. PCT/US04/24063	International filing date (day/month/year) 28 July 2004 (28.07.2004)
Applicant QUEST DIAGNOSTICS INVESTMENTS INCORPORATED	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the international application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the international search report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70.

For more detailed instructions, see the notes on the accompanying sheet.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.
3. ☐ With regard to the protest against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:
- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. Reminders

Shortly after the expiration of 18 months from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau as provided in Rules 90b*is.1* and 90b*is.3*, respectively, before the completion of the technical preparations for international publication.

The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. These comments would also be made available to the public but not before the expiration of 30 months from the priority date.

Within 19 months from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase until 30 months from the priority date (in some Offices even later); otherwise, the applicant must, within 20 months from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of 30 months (or later) will apply even if no demand is filed within 19 months.

See the Annex to Form PCT/IB/301 and, for details about the applicable time limits, Office by Office, see the PCT Applicant's Guide, Volume II, National Chapters and the WIPO Internet site.

Name and mailing address of the ISA/ US
Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22113-1450
Facsimile No. (571) 273-3201

Authorized officer

Nathan Newhouse

Telephone No. 571-272-4544

Form PCT/ISA/220 (January 2004)

(See notes on accompanying sheet)

PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 034827-3102	FOR FURTHER ACTION <small>see Form PCT/ISA/220 as well as, where applicable, item 5 below.</small>	
International application No. PCT/US04/24063	International filing date (day/month/year) 28 July 2004 (28.07.2004)	(Earliest) Priority Date (day/month/year) 28 July 2003 (28.07.2003)
Applicant QUEST DIAGNOSTICS INVESTMENTS INCORPORATED		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 9 sheets.



It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the Report

- a. With regard to the language, the international search was carried out on the basis of:



the international application in the language in which it was filed.



a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

- b. ☐ With regard to any nucleotide and/or amino acid sequence disclosed in the international application, see Box No. I.

2. ☐ Certain claims were found unsearchable (See Box No. II)

3. ☐ Unity of invention is lacking (See Box No. III)

4. With regard to the title,



the text is approved as submitted by the applicant.



the text has been established by this Authority to read as follows:

5. With regard to the abstract,



the text is approved as submitted by the applicant.



the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. With regard to the drawings,

- a. the figure of the drawings to be published with the abstract is Figure No. 1



as suggested by the applicant.



as selected by this Authority, because the applicant failed to suggest a figure.



as selected by this Authority, because this figure better characterizes the invention.

- b. ☐ none of the figures is to be published with the abstract.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US04/24063

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : B65D 25/00

US CL : 220/9.4

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 220/9.4, 4.28, 4.29, 6, 9.2, 9.3, 23.9, 592.2, 592.23, 915.2, 206/545, 383/110, 111, 119

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X --- Y	US 6,336,342 B1 (ZEDDIES) 08 January 2002 (08.01.2002), Figures 1, 3, 4, 6, 7, column 4, lines 1-29 and 44-52, column 5, lines 13-24	6, 11, 12, 14 ----- 6, 9-13, 15-24
X --- Y	US 2001/0030194 A1 (TATTAM) 18 October 2001 (18.10.2001), Figures 2A-2E and 4A-4C, paragraphs 0001-0004, 0011-0013 and 0051-0052	1, 2, 6-8 and 17 ----- 3-5 and 20-24
Y	US 6,582,124 B2 (MOGIL) 24 June 2003 (24.06.2003), Figures 1, 3, 7-10, column 4, lines 19-25 and 38-41, column 5, lines 3-17 and 40-41	6, 9-13, 15-24
Y	US 2003/0106895 A1 (KALAL) 12 June 2003 (12.06.2003), Figure2, paragraph 0022	4, 10, 24
Y	US 4,865,899 A (REICHERT) 12 September 1989 (12.09.1989), Figures 8-10, column 4, lines 26-30, column 6, lines 13-21	16
Y	US 4,585,159 A (TRAVIS) 29 April 1986 (29.04.1986), Figures 1-2, column 2, lines 21-23 and 29-30	17-19
Y	US 2001/0019024 A1 (BOYD-MOSS et al) 06 September 2001 (06.09.2001), Paragraphs 0002 and 0082)	3, 9, 23

☐ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"B" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T"

later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X"

document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y"

document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"Z"

document member of the same patent family

Date of the actual completion of the international search

21 November 2005 (21.11.2005)

Name and mailing address of the ISA/US

Mail Stop PCT, Attn: ISA/US
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Facsimile No. (571) 273-3201

Date of mailing of the international search report

11 JAN 2006

Authorized officer

Nathan Newhouse

Telephone No. 571-272-4544

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:
RICHARD J. WARBURG
FOLEY & LARDNER LLP
P.O. BOX 80278
SAN DIEGO, CA 92138-0278

PCT

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

(PCT Rule 43bis.1)

Applicant's or agent's file reference 034827-3102		Date of mailing (day/month/year) 11 JAN 2006
International application No. PCT/US04/24063		FOR FURTHER ACTION See paragraph 2 below
International filing date (day/month/year) 28 July 2004 (28.07.2004)	Priority date (day/month/year) 28 July 2003 (28.07.2003)	
International Patent Classification (IPC) or both national classification and IPC IPC(7): B65D 25/00 and US Cl.: 220/9.4		
Applicant QUEST DIAGNOSTICS INVESTMENTS INCORPORATED		

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☐ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

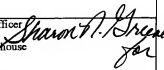
2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA/ US Mail Stop PCT, Attn: ISA/US Commissioner for Patents P.O. Box 1450 Alexandria, Virginia 22313-1450 Facsimile No. (571) 273-3201	Date of completion of this opinion 22 November 2005 (22.11.2005)	Authorized officer  Nathan Newhouse Telephone No. 571-272-4544
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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

International application No.

PCT/US04/24063

Box No. I Basis of this opinion

1. With regard to the language, this opinion has been established on the basis of:

- ☒ the international application in the language in which it was filed
- ☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b)).

2. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:

a. type of material

- ☐ a sequence listing
- ☐ table(s) related to the sequence listing

b. format of material

- ☐ on paper
- ☐ in electronic form

c. time of filing/furnishing

- ☐ contained in the international application as filed.
- ☐ filed together with the international application in electronic form.
- ☐ furnished subsequently to this Authority for the purposes of search.

3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table(s) relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.

4. Additional comments:

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Box No. V Reasoned statement under Rule 43 bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)

Claims 3-5, 9-10, 13, 15-16, 18-24 YES

Claims 1, 2, 6-8, 11-12, 14, 17 NO

Inventive step (IS)

Claims NONE YES

Claims 1-24 NO

Industrial applicability (IA)

Claims 1-24 YES

Claims NONE NO

2. Citations and explanations:

Please See Continuation Sheet

WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

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Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

V. 2. Citations and Explanations:

Claims 1, 2, 6-8, 17 lack novelty under PCT Article 33(2) as being anticipated by Tattam (US 2001/0030194 A1)

1. Regarding claims 1 and 2 Tattam provides a container with a soft-sided collapsible outer shell. (2, 3, Figures 2A-2E and 4A-4C, paragraphs 0011-0013 and 0051-0052) used for transporting hazardous materials (biochemical products) or organs (paragraphs 0001-0004). Positioning the hazardous material (organ) in the container would support the container from within, particularly when the end caps are not used (paragraph 0052).
2. Regarding claim 6, Tattam discloses a container with a soft-sided collapsible outer shell and a collapsible inner frame with rigid walls. (2, 3, Figures 2A-2E and 4A-4C, paragraphs 0011-0013 and 0051-0052).
3. Regarding claims 7 and 8, Tattam discloses the container may be used for transportation of hazardous materials (biochemical products) or organs (paragraph 0004).
4. Regarding claim 17, Tattam discloses the inner frame has rigid longitudinal walls and side walls (all 4 walls being the same dimension) that are collapsible to allow a reduction in the distance between the longitudinal walls (Figures 2A-E and 4A-C, column 4, paragraph 0051).
5. Claim 3 lacks an inventive step under PCT Article 33(3) as being obvious over Tattam in view of Boyd-Moss et al (US 2001/0019024 A1). Tattam discloses the method of claim 1 but does not teach that the outer shell satisfies IATA 602 requirements. Boyd-Moss et al discloses that it is known to construct a transport package that meets IATA 602 requirements to allow the package to be used for transport of hazardous goods (paragraphs 0002 and 0082). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the use materials and construction to meet IATA 602 as disclosed by Boyd-Moss et al in the container disclosed in claim 6 to allow the container to be used for transport of hazardous materials.
6. Claim 4 lacks an inventive step under PCT Article 33(3) as being obvious over Tattam in view of Kalal (US 2003/0106895 A1). Tattam discloses the method of claim 1 except for the vent holes. Kalal discloses a collapsible soft-sided container with a liner having vent holes in the outer shell to allow venting of air when the container is collapsed (42, Figure 2, paragraph 0022). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the use of vent holes in the outer shell as disclosed by Kalal in the container disclosed in claim 6 to allow venting of air when the container is collapsed.
7. Claim 5 lacks an inventive step under PCT Article 33(3) as being obvious over Tattam. Regarding claim 5, it would have been obvious to one of ordinary skill in the art to remove the hazardous material from the container at destination and collapse the container for more efficient storage or transport (paragraph 0020).

Claims 6, 11, 12 and 14 lack novelty under PCT Article 33(2) as being anticipated by Zeddies (US 6,336,342 B1).

8. Regarding claim 6, Zeddies discloses a container with a soft-sided collapsible outer shell and a collapsible inner frame with rigid walls. (Figures 1, 4, 6, 7, column 4, lines 1-29, column 5 lines 13-24).
9. Regarding claims 11 and 12, Zeddies discloses a plurality of walls integrally formed with a bottom and an open top (Figures 1 and 4) and a lid selectively secured to a vertical side wall (40, column 4, lines 44-52).
10. Regarding claim 14, Zeddies discloses the walls, including the bottom wall, are structurally reinforced (31, Figure 3, column 4, lines 26-28).

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US04/24063

Supplemental Box

In case the space in any of the preceding boxes is not sufficient.

11. Claims 6, 11-13 and 15 lack an inventive step under PCT Article 33(3) as being obvious over Mogil (US 6,582,124 B2) in view of Zeddies.
12. Regarding claim 6, Mogil discloses a container with a collapsible soft sided outer shell and a frame (liner) (Figures 1, 3, 7-9, column 4, lines 19-25). Mogil does not teach the use of a rigid inner frame. Zeddies discloses a collapsible rigid inner frame used with a collapsible outer shell to provide support to the outer shell. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the use of a collapsible rigid inner frame as disclosed by Zeddies in the container disclosed by Mogil to provide support for the soft sided collapsible outer shell.
13. Regarding claims 11-13, Mogil discloses a plurality of vertical walls integrally formed with a bottom (column 4, lines 29-38) and an open top with a lid (46) selectively secured to the vertical walls with a zipper (48, column 4, lines 38-41).
14. Regarding claim 15, Mogil discloses an outer fabric layer (88, Figure 10, column 5, lines 40-41) and a foam insulation layer (90).

Claim 10 lacks an inventive step under PCT Article 33(3) as being obvious over Mogil and Zeddies as applied to claim 6 in view of Kalal (US 2003/0106895 A1).

15. Mogil and Zeddies disclose the container of claim 6 except for the vent holes. Kalal discloses a collapsible soft sided container with a liner having vent holes in the outer shell to allow venting of air when the container is collapsed (42, Figure 2, paragraph 0022). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the use of vent holes in the outer shell as disclosed by Kalal in the container disclosed in claim 6 to allow venting of air when the container is collapsed.

Claim 9 lacks an inventive step under PCT Article 33(3) as being obvious over Mogil and Zeddies as applied to claim 6 in view of Boyd-Moss et al (US 2001/0019024 A1).

16. Mogil and Zeddies disclose the container of claim 6 but do not teach that the outer shell satisfies IATA 602 requirements. Boyd-Moss et al discloses that it is known to construct a transport package that meets IATA 602 requirements to allow the package to be used for transport of hazardous goods (paragraphs 0002 and 0082). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the use materials and construction to meet IATA 602 as disclosed by Boyd-Moss et al in the container disclosed in claim 6 to allow the container to be used for transport of hazardous materials.

Claim 16 lacks an inventive step under PCT Article 33(3) as being obvious over Mogil and Zeddies as applied to claim 15 in view of Reichert (US 4,865,899 A).

17. Mogil and Zeddies disclose the container of claim 15 but do not teach the outer fabric includes polyester. Reichert discloses a container for the transport of hazardous materials constructed from fabric comprising polyester that is selected for a high degree of imperviousness to hazardous materials. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the use of polyester in the fabric of the container as disclosed by Reichert in the container disclosed in claim 15 to provide a high degree of imperviousness to hazardous materials.

Claims 17-19 lack an inventive step under PCT Article 33(3) as being obvious over Mogil and Zeddies as applied to claim 6 in view of Travis (US 4,585,159 A).

18. Regarding claim 17, Mogil and Zeddies disclose the container of claim 6 with an inner frame having opposing rigid longitudinal walls and opposing collapsible side walls but do not teach that the side walls link the ends of the longitudinal walls and allow a reduction in a distance between the longitudinal walls when collapsed. Travis discloses a frame structure capable being used as the inner frame of the invention made of rigid material (Figures 1 and 2, column 2, lines 21-23) with the side walls linking the ends of the longitudinal walls and the walls being collapsible allowing a reduction in a distance between the longitudinal walls (column 2, lines 14 to 25). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the use of the frame structure as disclosed by Travis in the container disclosed by claim 6 to provide an inner frame that would be less bulky and fold flat with a thinner profile for handling and storage.
19. Regarding claim 18, Travis further discloses the bottom is pivotally engaged to the opposing rigid walls and pivots between open and collapsed positions (column 2, lines 29-30). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the use of the bottom panel pivotally attached to the rigid wall as disclosed by Travis to provide for the movement of the rigid bottom from an open position to the collapsed position to allow collapse of the frame.
20. Regarding claim 19, Mogil discloses a fastener that secures the outer shell in the collapsed position (Figures 7-9, column 5, lines 3-17). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the use of a fastener as disclosed by Mogil on the collapsed inner frame as well, to keep the frame secured in the collapsed position for ease of handling.

Claims 20-22 lack an inventive step under PCT Article 33(3) as being obvious over Mogil in view of Zeddies and Tattam.

21. Regarding claims 20 and 21, Mogil provides a container with a collapsible soft sided outer shell and a frame (liner) (Figures 1, 3, 7-9, column 4, lines 19-25). Mogil does not teach the use of a rigid inner frame. Zeddies discloses a collapsible rigid inner frame inserted in a collapsible outer shell to provide support to the outer shell. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the use of a collapsible rigid inner frame as disclosed by Zeddies in the container disclosed by Mogil to provide support for the soft sided collapsible outer shell.

22. Mogil does not teach positioning a hazardous material or organ in the assembled configuration. Tattam discloses a container with a soft-sided collapsible outer shell. (2, 3, Figures 2A-2E and 4A-4C, paragraphs 0011-0013 and 0051-0052) used for transporting

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US04/24063

Supplemental Box
In case the space in any of the preceding boxes is not sufficient.

hazardous materials (biochemical products) or organs (paragraphs 0001-0004). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the use of the assembled configuration of Mogil and Zeddies for transport of hazardous materials including organs as disclosed by Tattam to provide collapsible container with a removable frame for added container strength and collapsibility.

23. Regarding claim 22, it would have been obvious to one of ordinary skill in the art to remove the hazardous material from the container at destination, remove the inner frame and collapse the frame and the outer shell for more efficient storage or transport.

24. Claim 23 lacks an inventive step under PCT Article 33(3) as being obvious over Mogil, Zeddies and Tattam as applied to claim 20 in view of Boyd-Moss et al. Mogil, Zeddies and Tattam disclose the method of claim 20 but do not teach that the outer shell satisfies IATA 602 requirements. Boyd-Moss et al discloses that it is known to construct a transport package that meets IATA 602 requirements to allow the package to be used for transport of hazardous goods (paragraphs 0002 and 0082). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the use materials and construction to meet IATA 602 as disclosed by Boyd-Moss et al in the container disclosed in claim 20 to allow the container to be used for transport of hazardous materials.

25. Claim 24 lacks an inventive step under PCT Article 33(3) as being obvious over Mogil, Zeddies and Tattam as applied to claim 20 in view of Kalal. Mogil, Zeddies and Tattam disclose the method of claim 20 except for the vent holes. Kalal discloses a collapsible soft sided container with a liner having vent holes in the outer shell to allow venting of air when the container is collapsed (42, Figure 2, paragraph 0022). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have incorporated the use of vent holes in the outer shell as disclosed by Kalal in the container disclosed in claim 20 to allow venting of air when the container is collapsed.

26. Claims 1-24 meet the criteria set out in PCT Article 33(4), and thus have industrial applicability because the subject matter claimed can be made or used in industry.

NOTES TO FORM PCT/ISA/220 (continued)

The letter must indicate the differences between the claims as filed and the claims as amended. It must, in particular, indicate, in connection with each claim appearing in the international application (it being understood that identical indications concerning several claims may be grouped), whether

- (i) the claim is unchanged;
- (ii) the claim is cancelled;
- (iii) the claim is new;
- (iv) the claim replaces one or more claims as filed;
- (v) the claim is the result of the division of a claim as filed.

The following examples illustrate the manner in which amendments must be explained in the accompanying letter:

- 1 [Where originally there were 48 claims and after amendment of some claims there are 51]:
"Claims 1 to 29, 31, 32, 34, 35, 37 to 48 replaced by amended claims bearing the same numbers; claims 30, 33 and 36 unchanged; new claims 49 to 51 added."
- 2 [Where originally there were 15 claims and after amendment of all claims there are 11]:
"Claims 1 to 15 replaced by amended claims 1 to 11."
- 3 [Where originally there were 14 claims and the amendments consist in cancelling some claims and in adding new claims]:
"Claims 1 to 6 and 14 unchanged; claims 7 to 13 cancelled; new claims 15, 16 and 17 added." or
"Claims 7 to 13 cancelled; new claims 15, 16 and 17 added; all other claims unchanged."
- 4 [Where various kinds of amendments are made]:
"Claims 1-10 unchanged; claims 11 to 13, 18 and 19 cancelled; claims 14, 15 and 16 replaced by amended claim 14; claim 17 subdivided into amended claims 15, 16 and 17; new claims 20 and 21 added."

"Statement under Article 19(1)" (Rule 46.4)

The amendments may be accompanied by a statement explaining the amendments and indicating any impact that such amendments might have on the description and the drawings (which cannot be amended under Article 19(1)).

The statement will be published with the international application and the amended claims.

It must be in the language in which the international application is to be published.

It must be brief, not exceeding 500 words if in English or if translated into English.

It should not be confused with and does not replace the letter indicating the differences between the claims as filed and as amended. It must be filed on a separate sheet and must be identified as such by a heading, preferably by using the words "Statement under Article 19(1)."

It may not contain any disparaging comments on the international search report or the relevance of citations contained in that report. Reference to citations, relevant to a given claim, contained in the international search report may be made only in connection with an amendment of that claim.

Consequence if a demand for international preliminary examination has already been filed

If, at the time of filing any amendments and any accompanying statement, under Article 19, a demand for international preliminary examination has already been submitted, the applicant must preferably, at the time of filing the amendments (and any statement) with the International Bureau, also file with the International Preliminary Examining Authority a copy of such amendments (and of any statement) and, where required, a translation of such amendments for the procedure before that Authority (see Rules 55.3(a) and 62.2, first sentence). For further information, see the Notes to the demand form (PCT/PEA/401).

Consequence with regard to translation of the international application for entry into the national phase

The applicant's attention is drawn to the fact that, upon entry into the national phase, a translation of the claims as amended under Article 19 may have to be furnished to the designated/elected Offices, instead of, or in addition to, the translation of the claims as filed.

For further details on the requirements of each designated/elected Office, see the *PCT Applicant's Guide*, Volume II.